# MECLIZINE HCL- meclizine hcl tablet Aidarex Pharmaceuticals LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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**Meclizine HCl Caplets USP** 

Active Ingredient
(in each caplet)
Meclizine HCl 12.5 mg USP

Purpose

**Antiemetic** 

#### Uses

prevents and treats nausea, vomiting, or dizziness due to motion sickness

## **WARNINGS**

# Ask a doctor before use if you have

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

# **Ask a doctor or pharmacist before use if you are** taking sedatives or tranquilizers

# When using this product

- you may get drowsy
- avoid alcoholic drinks
- alcohol, sedatives & tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating a machinery

**If pregnant or breast-feeding,** ask a health professional before use.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

#### **Directions**

- adults and children 12 years and over: 2-4 caplets once daily
- children under 12 years: ask a doctor

#### Other Information

- each caplet contains: calcium 51 mg
- store at room temperature 15°-30°C (59°-86°F)

# **Inactive Ingredients**

croscarmellose sodium, dicalcium phosphate, magnesium stearate, microcrystalline cellulose, silicon

## **Questions or Comments**

Call **1-800-645-2158**, 9 am – 5 pm ET, Monday - Friday

# TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR BLISTER UNIT IS BROKEN OR DAMAGED

# Rugby® Duluth, Georgia 30097

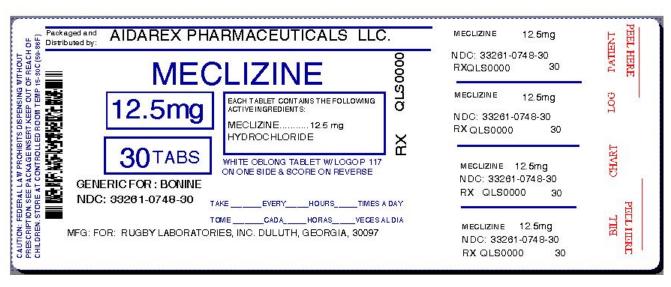
Repackaged By : Aidarex Pharmaceuticals LLC, Corona, CA 92880

## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 33261-0748-30

Meclizine HCl 12.5 mg Caplets USP Antiemetic

30 caplets



# MECLIZINE HCL meclizine hcl tablet Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:33261-748(NDC:0536-3985) Route of Administration ORAL Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength MECLIZINE HYDRO CHLO RIDE (UNII: HDP7W44CIO) (MECLIZINE - UNII:3L5TQ84570) MECLIZINE HYDROCHLO RIDE 12.5 mg

Inactive Ingredients			
Ingredient Name	Strength		
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)			
CALCIUM PHO SPHATE, DIBASIC, ANHYDRO US (UNII: L11K75P92J)			
MAGNESIUM STEARATE (UNII: 70097M6130)			
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
SILICON DIO XIDE (UNII: ETJ7Z6XBU4)			

Product Characteristics					
Color	WHITE	Score	2 pieces		
Shape	CAPSULE	Size	13mm		
Flavor		Imprint Code	AP;117		
Contains					

P	Packaging					
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date		
1	NDC:33261-748-30	30 in 1 BOTTLE, PLASTIC				
2	NDC:33261-748-60	60 in 1 BOTTLE, PLASTIC				
3	NDC:33261-748-90	90 in 1 BOTTLE, PLASTIC				

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC MONOGRAPH FINAL	part336	07/14/2006				

# Labeler - Aidarex Pharmaceuticals LLC (801503249)

Revised: 1/2014 Aidarex Pharmaceuticals LLC